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EXAMINER	
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ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/614,362	MEADE ET AL.	
	Examiner	Art Unit	
	JAMES H. ALSTRUM ACEVEDO	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31,34,35 and 37* is/are pending in the application.

4a) Of the above claim(s) *11-19 and 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10, 20-31, 35, and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-31, 34-35, and 37 are pending. Applicants amended claim 4. Applicants previously cancelled claims 32-33 and 36. Claims 9-31 and 34 are withdrawn from consideration as being drawn to non-elected subject matter. **Claims 1-10, 20-31, 35, and 37 are under consideration in the instant office action.** Receipt and consideration of Applicants' response to the species election requirement submitted 9/18/08 and Applicants' arguments remarks submitted 5/28/08 are acknowledged. The instant application is under examination by a different Examiner. All rejections not explicitly maintained in the instant office action have been withdrawn per Applicants' claim amendments and/or persuasive arguments.

Election/Restrictions

Applicants' election of a propellant-free solution or suspension as the form of the composition form is acknowledged. Claims 11-19 and 34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/18/08.

It is noted that on 2/27/04 a species election requirement was mailed requiring the election of a specific NK1 receptor antagonist, and that on 3/15/04 Applicants elected N-[2-(3,5-bis-trifluoromethylphenyl)ethyl]-2-{4-[(3-hydroxypropyl)-methylamino]-piperidin-1-yl}-N-methyl-2-phenylacetamide with traverse. The previous Examiner mailed a two-way restriction requirement on 2/28/05 and on 4/22/05 Applicants elected Group I, claims 1-8, 36 (now cancelled), and 37, with traverse.

In Applicants' 5/28/08 arguments/remarks, Applicants again traversed the two-way restriction mailed on 2/28/05. Applicants argued that the characterization of the claims of the two groups as unrelated was improper, because many of the claims in the non-elected group ultimately depend from claim 1, which was included in Applicants' elected group. The Examiner agrees with Applicants that the two groups cannot properly be characterized as corresponding to unrelated inventions. The restriction requirement is withdrawn. The species elections of record are maintained at this time.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 20-31, 35, and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the *written description requirement*. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Determination of Claim Scope

Claims 1 and 37 of the instant application claim (A) a pharmaceutical composition comprising (i) one or more anticholinergics of formula 1, including a solvate or hydrate thereof and (ii) one or more NK1 receptor antagonist, including a solvate or hydrate thereof and (B) a method of treatment of chronic obstructive pulmonary diseases (COPD) comprising administering (i) and (ii) contained in separate pharmaceutical formulations, respectively.

Review of Applicants' Disclosure

The instant specification does not disclose, to which solvates or hydrates of any anticholinergic of formula 1 or any NK1 receptor antagonist Applicants are referring. Applicants' specification does not disclose how to make any particular solvate or hydrate of any anticholinergic of formula 1 or any NK1 receptor antagonist, nor do Applicants depict chemical structures of any anticholinergic of formula 1 or any NK1 receptor antagonist as any particular hydrate or solvate in their disclosure.

Possession Based on Ordinary Skilled Artisan's Determination/ State of the Prior Art

It is generally accepted in the art that the formation of a particular solvate or hydrate for a given compound or series of compounds is unpredictable (see Vippagunta et al. "Crystalline Solids," *Advanced Drug Delivery Reviews*, **2001**, *48*, pp 18), therefore, the generic reference to a solvate of either [specify species] in the instant specification does not provide adequate written support for claims drawn to any solvate or hydrate of these compounds. An ordinary skilled artisan would conclude that Applicants were not in possession of any particular solvate or hydrate of any anticholinergic of formula 1 or any NK1 receptor antagonist of the claimed composition and method. Furthermore, because Applicants' generic reference to solvates or hydrates of any anticholinergic of formula 1 or any NK1 receptor antagonist does not permit the ordinary skilled artisan to clearly envisage which specific solvate or hydrate, if any, of any anticholinergic of formula 1 or any NK1 receptor antagonist were in Applicants' possession, the only reasonable conclusion said artisan would make was that Applicants were not in possession of solvates and/or hydrates of any anticholinergic of formula 1 or any NK1 receptor antagonist and had not reduced to practice the preparation, isolation, and characterization of said solvates and hydrates.

The remaining claims are rejected as depending from a rejected claim.

Claims 1-10, 20-31, 35, and 37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions comprising components (a)-(c) in the form of enantiomers, racemates, mixtures of enantiomers, and physiologically acceptable acid addition salts thereof, does not reasonably provide enablement for compositions comprising solvates or hydrates of any one or more of components (a)-(c).

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

An analysis based upon the Wands factors is set forth below.

To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In *Genentech Inc. v. Novo Nordisk* 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997); *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993),. See also *Amgen Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re Fisher* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Further, in *In re Wands* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court stated:

> Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman (230 USPQ 546, 547 (Bd Pat App Int 1986)). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Breadth of Claims

Applicants' claims are broad with regards to the subgenera of solvates, hydrates, enantiomers, racemates, and mixtures of enantiomers of one or more of components any anticholinergic of formula 1 or any NK1 receptor antagonist.

Nature of the invention/State of the Prior Art

Claims 1 and 37 of the instant application claim (A) a pharmaceutical composition comprising (i) one or more anticholinergics of formula 1, including a solvate or hydrate thereof

and (ii) one or more NK1 receptor antagonist, including a solvate or hydrate thereof and (B) a method of treatment of chronic obstructive pulmonary diseases (COPD) comprising administering (i) and (ii) contained in separate pharmaceutical formulations, respectively, are representative of the nature of Applicants' invention. It is generally accepted in the art that the formation of a particular solvate or hydrate for a given compound or series of compounds is unpredictable (see Vippagunta et al. "Crystalline Solids," *Advanced Drug Delivery Reviews*, **2001**, *48*, pp 11 and 18).

Level of One of Ordinary Skill & Predictability/Unpredictability in the Art

The level of a person of ordinary skill in the art is high, with ordinary artisans having advanced medical and/or scientific degrees (e.g. M.D., Ph.D., Pharm. D. or combinations thereof). There is a general lack of predictability in the pharmaceutical art. *In re Fisher*, 427, F. 2d 833, 166, USPQ 18 (CCPA 1970). The art is especially unpredictable with regards to the existence and formation of particular polymorphs and pseudopolymorphs (e.g. hydrates and solvates) of chemical compounds, as set forth above by the teachings of Vippagunta et al.

Guidance/Working Examples

Applicants provide no guidance or working examples about the preparation of any solvate or hydrate of Claims 1 and 37 of the instant application claim (A) a pharmaceutical composition comprising (i) one or more anticholinergics of formula 1, including a solvate or hydrate thereof and (ii) one or more NK1 receptor antagonist, including a solvate or hydrate thereof and (B) a method of treatment of chronic obstructive pulmonary diseases (COPD)

comprising administering (i) and (ii) contained in separate pharmaceutical formulations, respectively.

In conclusion, the specification, while being enabling for compositions comprising components (i) and (ii) in the form of enantiomers, racemates, and mixtures of enantiomers, and methods of treating COPD by administering said components, does not reasonably provide enablement for compositions comprising solvates or hydrates of Claims 1 and 37 of the instant application claim (A) a pharmaceutical composition comprising (i) one or more anticholinergics of formula 1, including a solvate or hydrate thereof and (ii) one or more NK1 receptor antagonist, including a solvate or hydrate thereof and (B) a method of treatment of chronic obstructive pulmonary diseases (COPD) comprising administering (i) and (ii) contained in separate pharmaceutical formulations, respectively.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.

3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10, 20-26, 28-31, 35, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meissner et al. (US 2002/0115680) in view of Dollinger et al. (WO 02/32865) (IDS reference) and Podolsky (US 2003/0185838) (already of record).

Applicants Claim

Applicants claim (A) a pharmaceutical composition comprising (i) one or more anticholinergics of formula 1, including a solvate or hydrate thereof and (ii) one or more NK1 receptor antagonist, including a solvate or hydrate thereof and (B) a method of treatment of chronic obstructive pulmonary diseases (COPD) comprising administering (i) and (ii) separately or together in a pharmaceutical formulation to a patient in need thereof.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Meissner teaches **the administration of anticholinergic compounds of formula I, to treat chronic obstructive pulmonary disease (COPD)** (title; abstract; [0004], [0172]; [0184]; [0188]; and claim 7). **Applicants' specific anticholinergic of formula 1 is disclosed explicitly by Meissner as a compound of particular importance ([0049] and [0051])**. Meissner discloses the synthesis of Applicants' anticholinergic compound of formula 1 in Example 1([0103]-[[0108]). Meissner discloses that pharmaceutical formulations of the invented anticholinergic compounds may be in the form of solutions [0184] and the solutions are prepared in the usual way with the addition of isotonic agents (e.g. NaCl), preservatives (e.g. p-hydroxybenzoates), stabilizers (e.g. alkali salts of EDTA), diluent (e.g. water), and organic solvents [0186]. An exemplified **aqueous propellant-free formulation is disclosed in Example C and comprises active substance (i.e. Meissner's invented anticholinergic compounds), sodium chloride (i.e. an isotonic agent), and water (i.e. a diluent)** (between paragraphs [0193]-[0194]). The active substance is prepared by dissolution in water, optionally adjusting the pH to a value of 5.5 to 6.5, and addition of sodium chloride [0194]. Example E discloses an **aqueous formulation with a pH of 3.4 comprising active substance (333.3 mg), formoterol fumarate (333.3 mg), benzalkonium chloride (10.0 mg), EDTA (50.0 mg), 1N HCl (added in an amount sufficient to result in a pH of 3.4)** [0195]-[0196]. In general, suitable amounts of Meissner's invented anticholinergic compounds are in the range of **0.05-90% w/w [0184] or in an amount from 1-1,000 mg** [0189]. The invented anticholinergic compounds **are characterized by high efficacy even in the microgram amount** [0189]. Syrups or elixirs (i.e. liquid formulations) comprising the active substances may additionally contain sweeteners (e.g. saccharine, glycerol, or sugar) and **flavorings** (e.g. vanilla orange

extract) [0185]. The compositions may also contain **suspension adjuvants, wetting agents, and preservatives** [0185].

Dollinger discloses **Applicants' elected NK1 receptor antagonist and its synthesis on pages 8 and 13 and in Dollinger's claim 9**. The synthesis of Applicants' elected NK1 receptor antagonist compound is disclosed in Example 1 (pg. 12, line 25 through pg. 14, line 23). Dollinger discloses that the invented neurokinin receptor antagonists are NK1 receptor antagonists (claim 1 and the partial English translation of the International Search Report).

Podolsky teaches methods and compositions for treatments of lesions of the respiratory epithelium comprising trefoil peptide alone or in combination with additional therapeutic agents (e.g. **neurokinin receptor antagonists**) (title; abstract; [0010]-[0013], and claim 28), and expressly teaches the administration of neurokinin receptor antagonists in combination with trefoil peptides **in the treatment of COPD** (see [0010]; [0032]; and claims 1, 5, and 16). **Neurokinin receptor antagonists and cholinergic receptor antagonists (i.e. anticholinergics) are explicitly identified as being bronchodilating agents** [0065].

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Meissner lacks the teaching of compositions comprising NK1 receptor antagonists and the administration of said compounds to treat COPD. This deficiency is cured by the teachings of Dollinger and Podolsky.

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been prima facie obvious to modify Meissner's compositions to comprise one or more neurokinin 1 (NK1) receptor antagonist (Dollinger), because neurokinin receptor antagonists are known and are indicated for the treatment of COPD (Podolsky). An ordinary skilled artisan would have been motivated to combine the prior art teachings because Meissner's anticholinergic compounds are indicated for the treatment of COPD and neurokinin antagonists, such as, Dollinger's neurokinin 1 antagonists, are indicated for the treatment of COPD as well. It is generally considered *prima facie* obvious to combine two compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. See *In re Kerkhoven*, 626, F.2d 848, 205 USPQ 1069 (CCPA 1980). An ordinary skilled artisan would have had a reasonable expectation of successfully combining the prior art compositions to obtain formulations suitable for the treatment of COPD, because Meissner's invented anticholinergic compounds are indicated for the treatment of COPD and neurokinin antagonists, such as Dollinger's invented neurokinin antagonists are indicated for the treatment of COPD.

Regarding the amounts of the anticholinergic compounds of Applicants' formula 1 and the NK1 receptor antagonists, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization

of ingredient amounts would have been obvious at the time of applicant's invention. It is noted that Applicants' specification contains no data or other objective evidence regarding the properties of the claimed compositions and associated methods of treating COPD. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Response to Arguments

Applicants' arguments with respect to claims 1-10, 20-26, 28-31, 35, and 37 have been considered but are moot in view of the new ground(s) of rejection.

It is noted however, that Applicants' alleged certain deficiencies in Podolsky, namely that Podolsky targets the treatment of lesions caused by varies disease conditions, including COPD, and that COPD does not always result in lesions. This is found unpersuasive, because the treatment of a disease includes the treatment of its symptoms, such as lesions of the pulmonary epithelia caused by COPD, and because Applicants' claims do not exclude the treatment of COPD patients that lack pulmonary epithelial lesions. Thus, the above rejection remains proper.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meissner et al. (US 2002/0115680) in view of Dollinger et al. (WO 02/32865) (IDS reference) and Podolsky (US 2003/0185838) (already of record) as applied to claims 1-10, 20-26, 28-31, 35, and 37 above, and further in view of Freund et al. (US 2001/0008632).

Applicants Claim

Applicants claim a pharmaceutical composition, as described above, further comprising an antioxidant selected from ascorbic acid, Vitamin A, Vitamin E, or tocopherols.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Meissner, Dollinger, and Podolsky are set forth above.

Freund teaches aqueous propellant-free pharmaceutical solutions comprising **any substance suitable for the treatment of respiratory diseases by inhalation administration** (title; abstract; [0001]; [0007]), such as betamimetics, **anticholinergics,** antiallergics, etc. Usually pharmaceuticals intended for inhalation are dissolved in **an aqueous or ethanolic solution**, according to the solution characteristics of the active substance [0004]. Other suitable solvents for inclusion in the formulations include **isopropyl alcohol, polyethylene glycol, glycerol**, etc. [0005]. The compositions comprise complexing agents, such as EDTA, disodium EDTA, citric acid, ascorbic acid, and nitriloacetic acid [0011]. The compositions **may also comprise additional adjuvants, such as preservatives (e.g. benzalkonium chloride)** [0010].

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Meissner lacks the teaching of compositions comprising an antioxidant, such as, ascorbic acid. This deficiency is cured by the teachings of Freund.

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been prima facie obvious to modify Meissner's compositions to comprise ascorbic acid in lieu of or in addition to EDTA, because ascorbic acid is a well-known complexing agent (Freund) and Meissner teaches that the invented compositions may comprise complexing agents, such as EDTA. An ordinary skilled artisan would have been motivated to add ascorbic acid to Meissner's invented compositions and would have had a reasonable expectation of successfully obtaining suitable formulations, because ascorbic acid is a well-known complexing agent and would reasonably be expected to function as a complexing agent alone or in combination with other complexing agents, such as EDTA. It is generally considered *prima facie* obvious to combine two compounds each of which is taught by the prior art to be useful for the same purpose (e.g. complexing agents), to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. See *In re Kerkhoven*, 626, F.2d 848, 205 USPQ 1069 (CCPA 1980). Regarding the recitation in Applicants' claim that ascorbic acid is an antioxidant, this is merely an intended use of ascorbic acid, as well as a property of ascorbic acid. A compound and its properties are inseparable. Thus, the prior art is suggestive of compositions comprising ascorbic acid. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Response to Arguments

Applicants' arguments with respect to claim 27 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Anthes et al. ("SCH 206272: a potent, orally active tachykinin NK1, NK2, and NK3 receptor antagonist," 2002, European Journal of Pharmacology, 450, pp 191-202) is relevant prior art, because it teaches a known NK1 receptor antagonist, SCH 206272, and that SCH 206272 may have beneficial effects in the treatment of diseases, such as asthma and COPD (e.g. title and abstract). Doi et al. (JP02002249432A) is relevant prior art, because it teaches a genus of NK-1 receptor antagonits in combination with a NK-2 receptor antagonist and an anticholinergic to treat COPD (English Abstract Only).

Claims 1-10, 20-31, 35, and 37 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-5:00 and Saturdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/James H Alstrum-Acevedo/
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